

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the: Bradley Moore et al.
Application of

Serial No. : 10/821,284

Filed : April 9, 2004

Entitled : **INSTRUMENTS AND METHODS FOR
MINIMALLY INVASIVE SPINE SURGERY**

Docket No. : DEP5292USNP

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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Depuy Spine, Inc. of Raynham, Massachusetts, a Johnson & Johnson company. Depuy Spine, Inc. derives its rights in this application by virtue of an assignment of the application by the inventors to Depuy Spine, Inc. as recorded on April 9, 2004 at Reel 015217, Frame 0362.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 37-47 are currently pending in the present application, Serial Number 10/821,284. Accordingly, claims 37-47 are subject to appeal.

IV. STATUS OF AMENDMENTS

On October 22, 2009, prior to the filing of the present Appeal Brief, Appellant submitted claim amendments under 37 CFR 41.33(a) to dependent claim 38, 42, and 43, to address objections set forth in the April 23, 2009, Office Action. Appellant is awaiting entry of the October 22, 2009, claim amendments by the Examiner.

A copy of the pending claims is attached as Appendix A. Pursuant to 37 CFR 41.37(c)(2), the pending claims of Appendix A do not incorporate the October 22, 2009, claim amendments.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a minimally invasive surgical method. The method includes making a first incision in a patient. *See, e.g.*, p. 5, lines 29-33 (para. [22]) and p. 6, lines 1-7 (para. [22]). The method also includes inserting a retractor having a plurality of expandable retractor blades into the first incision and expanding the retractor by separating the retractor blades. *See, e.g.*, p. 6, lines 21-30 (para. [24]). The method also includes advancing a first anchor through the expanded retractor to a first anchor site on a first vertebra and advancing a second anchor through the expanded retractor to a second anchor site on a second vertebra adjacent the first vertebra. *See, e.g.*, p. 5, lines 18-33 (paras. [21], [22]) and p. 6, lines 1-7 (para. [22]). The method also includes making a percutaneous incision in the patient and advancing a third anchor through the percutaneous incision to a third anchor site on a third vertebra adjacent one of the first and second vertebra. *See, e.g.*, p. 7, lines 16-24 (para. [26]). The method also

includes positioning a first end of a spinal rod in the expanded retractor, advancing the first end of the spinal rod subcutaneously to the third anchor, and coupling the spinal rod to the first anchor, the second anchor, and the third anchor. *See, e.g.*, p. 9, lines 2-13 (para. [29]).

Independent claim 47 recites a minimally invasive surgical method. The method includes implanting a first anchor and second anchor in a first vertebra and a second vertebra, respectively, through an expanded surgical retractor positioned in a first incision. *See, e.g.*, p. 5, lines 18-33 (paras. [21], [22]) and p. 6, lines 1-7 and lines 21-23, (paras. [22], [24]). The method also includes percutaneously positioning a third anchor in a third vertebra adjacent one of the first vertebra and the second vertebra through a percutaneous incision distinct from the first incision. *See, e.g.*, p. 7, lines 16-24 (para. [26]). The method also includes advancing the first end of a spinal rod subcutaneously from the first incision to the third anchor and coupling the spinal rod to the first anchor, the second anchor, and the third anchor. *See, e.g.*, p. 9, lines 2-13 (para. [29]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A.** Whether the Examiner improperly rejects claim 37 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Publication No. 2003/0073998 of Pagliuca in view of U.S. Patent Application Publication No. 2005/0065517 of Chin and U.S. Patent Application Publication No. 2004/0230100 of Shluzas.
- B.** Whether the Examiner improperly rejects claim 47 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent Application Publication No. 2003/0073998 of Pagliuca in view of U.S. Patent Application Publication No. 2005/0065517 of Chin and U.S. Patent Application Publication No. 2004/0230100 of Shluzas.

VII. ARGUMENT

- A. Rejection of Claim 37 Pursuant to 35 U.S.C. §103(a) Over Pagliuca in view of Chin and Shluzas**

1. The Scope and Content of Pagliuca

Pagliuca describes methods for fixing vertebrae of a patient at a surgical site using a cannula or expandable conduit, and adjustable support for the cannula, and the inserting of surgical instruments, a viewing device, such as an endoscope, a spinal implant or fusion device, and a vertebral fixation assembly through the cannula to the surgical site. *See* Pagliuca, para.

[0107]. During an endoscopic surgical procedure, the cannula is inserted into the body of a patient in a contracted condition and a second tubular portion is then expanded to create an endoscopic operating field at a surgical site. *See* Pagliuca, paras. [0122], [0123]. The cannula or expandable conduit may be used to perform an operation that secures two vertebrae together. *See* Pagliuca, para [0171]. In such procedures, fasteners 4600 may be attached to the vertebra V through an expandable conduit 1020 and a fixation element 4650 may be delivered through the expandable conduit 1020 and connected to the housing portions 4604 of the fasteners 4600. *See* Pagliuca, para [0273], [0274] and FIGURE 90. In such procedures, an endoscope 1502 is used by the surgeon to allow direct visualization of the placement of the fasteners and the fixation element into the fasteners. *See* Pagliuca, para [0273], [0274] and FIGURE 90. The expandable conduit 1020 includes cut-out portions 1056 and 1058 provided in the skirt portion 1024 of the conduit that allow an end 4652 of the elongated member 4650 to extend beyond the operative space without raising or repositioning the skirt portion. *See* Pagliuca, para [0277] and FIGURE 90.

2. *The Scope and Content of Chin*

Chin describes percutaneous minimally invasive spinal surgical techniques. Small incisions are made in the patient's skin 70 along the spine 80 creating skin openings 92a-92f (302). *See* Chin, para. [0063]. Guide wires 96a-96f are advanced through the skin openings 92a-92f, respectively, through the underlying tissue and into the bony anatomy of a vertebral element such as a pedicle (304). *See* Chin, para. [0063]. The wires can be inserted under fluoroscopic vision or as an open procedure under direct vision. *See* Chin, para. [0063]. A tissue dilator is advanced over the guide wires (306) to develop a channel from the skin to the fixation point of the guide wire. *See* Chin, para. [0063]. A fixation device, such as a pedicle screw 140, is attached to each of the working portals 94a-94f and the portal assemblies 94a-94f including the pedicle screw 140 are inserted over the guide wires 96a-96f, respectively, and into the bone. *See* Chin, para. [0063] and FIG. 6. Once the portals are in position, the guide wires 96a-96f are removed (314) and the above steps are repeated for as many pedicle screws and openings that are required (315). *See* Chin, para. [0063]. A pair of curved facial scissors 150 or curved scalpel is then inserted through the working channel 115 of portal 94c or through channel 135 of side portal 130 and advanced beneath the patient's skin 70 while cutting through the lumbodorsal fascia 75 until the scissor tips enter the next adjacent portal 94b through the slot 118, as in FIG. 9

(316). *See* Chin, para. [0063]. A carrier device 160 is then inserted through channel 135 of side portal 130 across the soft tissues either above or below the level of the lumbodorsal fascia 75 until the tip of the carrier enters the next adjacent portal 94b (318). *See* Chin, para. [0063]. A connecting device 170, such as a cylindrical rod, plate, articulating device, or biologic substances is placed in the semi-cylindrical front portion 162 either before insertion or after insertion and is brought in the tissue area between portal 94c and 94b. *See* Chin, para. [0063]. This step can be repeated between multiple adjacent portals or across sets of portals for segmental fixation. *See* Chin, para. [0063] and Figures 11-13. After the connecting device 170 is engaged within the portals, the carrier device 160 is retracted from the portals and the connecting device 170 is then inserted to the base of the portals or until it engages the pedicle screws 140. *See* Chin, para. [0063] and Figures 11-13.

This technique “provides the ability to sequentially connect a fixation device percutaneously between more than two points simultaneously and only directly visualizing the fixation points and not the entire connecting device. This scalable feature is currently a major limitation of other minimally access devices.” *See* Chin, Para. [0015].

3. *The Scope and Content of Shluzas*

Shluzas describes a system for minimally invasive postero-lateral spinal surgery. *See* Shluzas, para. [0129]. The system includes an access device that can be expanded to provided a working space and sufficient visibility to manipulate surgical instruments and treat the underlying body structures. *See* Shluzas, para. [0130] One embodiment of the access device 100 includes a distal portion that is expandable and provides first and second overlapping skirt members 114, 116. *See* Shluzas, para. [0145]. The amount of expansion of the access device 100 is determined by the amount of overlap of the first skirt member 114 and the second skirt member 116. *See* Shluzas, para. [0145].

4. *The Examiner’s Rejection of Claim 37*

Claims 37-46 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Pagliuca in view of Chin and Shluzas. The Examiner argues that Pagliuca discloses the subject matter of claim 37 except for:

- a retractor having a plurality of expandable retractor blades,
- expanding the retractor by separating the retractor blades,

- making a percutaneous incision in the patient,
- advancing a third anchor through the percutaneous incision to a third anchor site on a third vertebra adjacent one of the first and second vertebra, and
- advancing the first end of the spinal rod subcutaneously to the third anchor.

The Examiner asserts that Chin discloses making a percutaneous incision in the patient, advancing a third anchor through the percutaneous incision to a third anchor site on a third vertebra adjacent one of the first and second vertebra, and advancing the first end of the spinal rod subcutaneously to the third anchor. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Pagliuca making a percutaneous incision in the patient, advancing a third anchor through the percutaneous incision to a third anchor site on a third vertebra adjacent one of the first and second vertebra, and advancing the first end of the spinal rod subcutaneously to the third anchor in view of Chin “to perform minimally invasive spine surgery.” *See* Office Action, page 5.

The Examiner asserts that the method disclosed in Chin is an improvement over the method disclosed in Pagliuca because the incisions in the Chin method are smaller, thus, less invasive, and the Chin method is more useful in larger surgeries in which more than three bone anchors are used on either side of the spine. The Examiner asserts that Chin would allow for the installation of many bone anchors without requiring a long incision or multiple larger incisions for expandable retractor blades, while also maintaining a larger workspace inside the body and also use an endoscope. The Examiner further argues that surgeons familiar with the techniques of Pagliuca may initially use the Pagliuca method in combination with the Chin method, as asserted by the Examiner, to gain familiarity with the instrumentation of the Chin method.

The Examiner asserts that Schluzas discloses a retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades. The Examiner asserts that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to the perform the method of Pagliuca with a retractor having a plurality of expandable retractor blades and expanding the retractor by separating the retractor blades in view of Schluzas, since such is a functional equivalent of the single blade expandable retractor disclosed in Pagliuca and would provide the predictable result of allowing access into a working space within the body.

5. *Modifying Pagliuca In View Of Chin Renders Pagliuca Unsatisfactory For Its Intended Purpose*

“Although predictability is a touchstone of obviousness, the ‘predictable result’ discussed in KSR refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose.” DePuy Spine, Inc., et al. v. Medtronic Sofamor Danek, Inc. Appeal Nos. 2008-1240, -1253, -1401 (Fed. Cir. 2009), citing KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739-40 (2007). “The Supreme Court went on to state that “when a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.”” Id. (emphasis in original) “The opposite conclusion would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention ... An inference of nonobviousness is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.” Id. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” Id., quoting Ricoh Co., Ltd. v. Quanta Computer Inc., 550 F.3d 1325, 1332 (Fed. Cir. 2008) (quoting In re Kahn, 441 F.3d 977, 990 (Fed. Cir. 2006)).

Pagliuca and Chin teach away from the combination proposed by the Examiner such that one of ordinary skill in the art would have been deterred from combining the methods of Pagliuca and Chin in the manner asserted by the Examiner.

In the background, Pagliuca describes one, and only one, problem intended to be addressed - prior art endoscopic based surgical systems were suitable for small surgical sites but, before Pagliuca’s method, according to Pagliuca, such endoscopic systems had not been developed for fixing vertebra. *See* Pagliuca, paras. [0003]-[0006]. Throughout its lengthy description, Pagliuca describes the importance of creating a significantly larger working space, compared with conventional endoscopic based surgical systems, for the surgeon within the body, the larger working space being provided by the access devices disclosed in Pagliuca. *See* Pagliuca, para. [0122], [0123], [207], [235], [0246]. One advantage of such a larger working space, according to Pagliuca, is the creation of an “endoscopic operating field at the surgical

site” that allows the surgeon to directly visualize the entire working space. *See* Pagliuca, para. [0123]. Pagliuca further describes an extensive support system 120 for supporting an endoscope and describes the presence and use of an endoscope to provide direct visualization of the larger working space provided by the access devices. *See, e.g.,* Pagliuca, para. [0124]-[0126]. In procedures for fixing vertebrae, all of the implants are positioned relative to the vertebrae through the access device in the large, expanded working space provided by the access device and under direct visualization of an endoscope. In one embodiment of Pagliuca, for example, three fasteners 4600 are attached to the vertebra V through the expandable conduit 1020 and a fixation element 4650 is delivered through the expandable conduit 1020 and connected to the housing portions 4604 of the three fasteners 4600. The placement of the fasteners 4600 and the fixation element 4650 is done under direct visualization through endoscope 1502. *See* Pagliuca, para [0273], [0274] and FIGURE 90. One of ordinary skill in the art when reading Pagliuca could only conclude that a larger working space that permits direct visualization of the surgical site with an endoscope was a critical component of the teachings of Pagliuca and that such teachings were Pagliuca’s contributions over prior art endoscopic based surgical systems.

In contrast, Chin describes percutaneous minimally invasive surgical procedures that includes inserting anchors, pedicle screws 140, through separate percutaneous incisions 92a-92f and advancing a connecting device 170, such as a cylindrical rod, subcutaneously to each of the separately positioned pedicle screws 140. These procedures provide “the ability to sequentially connect a fixation device percutaneously between more than two points simultaneously and only directly visualizing the fixation points and not the entire connecting device. This scalable feature is currently a major limitation of other minimally access devices.” *See* Chin, para. [0015] (emphasis added). The “other minimally invasive devices” described in the background of Chin include the endoscopic minimally invasive spinal systems described in U.S. Patent Nos. 5,792,044 and 5,902,231, which are similar to the endoscopic minimally invasive spinal systems described in Pagliuca. *See* Chin, para. [0006]. According to Chin, “[a]nother advantage of this invention is the ability to perform a direct approach to the fixation of two or more points with the option to place the connecting device beneath the lumbodorsal fascia or through an incision, created by instruments in the lumbodorsal fascia between each fixation points rather than being confined to go beneath the fascia between the fixation points or through a larger opening in the fascia which requires greater tissue expansion and results in greater postoperative pain.” *See*

Chin, para. [0015] (emphasis added). One of ordinary skill in the art when reading Chin would conclude that Chin's discredits prior art endoscopic systems like the system in Pagliuca, and that Chin's contributions over such systems resulted in increased scalability, minimized tissue expansion from the creation of a large working space, and the resultant trauma caused by such expansion, and, in doing so, limited the surgeons ability to directly visualize the placement of the fixation device (e.g., the spinal rod) during the procedure.

Pagliuca, thus, on the one hand teaches the critical importance of a creating a large working space within the access device by expanding the access device, thereby, permitting direct visualization of the working space through an endoscope, and placement of all of the bone anchors and the spinal fixation through the access device (in the large working space) under direct visualization. On the other hand, Chin discredits the Pagliuca like endoscopic minimally invasive system (as having "limited scalability" and increased tissue expansion) and describes a minimally invasive system that lacks an expandable access device, and, thus, lacks a large working space, and does not permit direct visualization of the entire procedure. Instead, Chin describes inserting anchors, pedicle screws 140, through separate percutaneous incisions 92a-92f and advancing a connecting device 170, such as a cylindrical rod, subcutaneously, without direct visualization, to each of the separately positioned pedicle screws 140. One of ordinary skill in the art would appreciate these contradictory teachings of Pagliuca and Chin and for this reason would be deterred from combining their teachings in the manner asserted by the Examiner.

At most, one of ordinary skill in the art, after evaluating the contradictory teachings of Pagliuca and Chin, would select one of the systems/techniques as a whole or complete replacement or substitute for the other. For example, if the ordinary skilled artisan considered the systems and methods of Chin to be an improvement over the systems and methods of Pagliuca, as asserted by the Examiner, the ordinary skilled artisan would chose to use the entire system and method of Chin (positioning all of the bone anchors through separate percutaneous incisions and advancing the connecting device subcutaneously) rather than combining aspects of Pagliuca and Chin as proposed by the Examiner. Only with the benefit of the Appellant's disclosure would the ordinary skilled artisan know to combine the teachings of Pagliuca and Chin in the manner proposed by the Examiner.

For this reason, independent claim 37, as well as claims 38-46 dependent thereon, distinguishes over Pagliuca and Chin and Shluzas, and represents allowable subject matters. Appellant respectfully requests withdrawal of the rejection.

B. Rejection of Claim 47 Pursuant to 35 U.S.C. §103(a) Over Pagliuca in view of Chin and Shluzas

1. The Examiner's Rejection of Claim 47

Claim 47 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Pagliuca in view of Chin and Shluzas. The Examiner argues that Pagliuca discloses the subject matter of claim 47 except for:

- percutaneously positioning a third anchor in a third vertebra adjacent one of the first vertebra and the second vertebra through a percutaneous incision distinct from the first incision, and
- advancing the first end of a spinal rod subcutaneously from the first incision to the third anchor

The Examiner asserts that Chin discloses percutaneously positioning a third anchor in a third vertebra adjacent one of the first vertebra and the second vertebra through a percutaneous incision distinct from the first incision and advancing the first end of a spinal rod subcutaneously from the first incision to the third anchor. The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Pagliuca percutaneously positioning a third anchor in a third vertebra adjacent one of the first vertebra and the second vertebra through a percutaneous incision distinct from the first incision and advancing the first end of a spinal rod subcutaneously from the first incision to the third anchor in view of Chin “to perform minimally invasive spine surgery.” *See* Office Action, page 5.

The Examiner asserts that method disclosed in Chin is an improvement over the method disclosed in Pagliuca because the incisions are smaller, thus less invasive, and the Chin method is more useful in larger surgeries in which more than three bone anchors are used on either side of the spine. The Examiner asserts Chin would allow for the installation of many bone anchors without requiring a long incision or multiple larger incisions for expandable retractor blades, while also maintaining a larger workspace inside the body and also use an endoscope. The

Examiner further argues that surgeons familiar with the techniques of Pagliuca may initially use the Pagliuca method in combination with the Chin method, as asserted by the Examiner, to gain familiarity with the instrumentation of the Chin method.

2. *Modifying Pagliuca In View Of Chin Renders Pagliuca Unsatisfactory For Its Intended Purpose*

“Although predictability is a touchstone of obviousness, the ‘predictable result’ discussed in KSR refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose.” DePuy Spine, Inc., et al. v. Medtronic Sofamor Danek, Inc. Appeal Nos. 2008-1240, -1253, -1401 (Fed. Cir. 2009), citing KSR Int’l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739-40 (2007). “The Supreme Court went on to state that “when a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.”” Id. (emphasis in original) “The opposite conclusion would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention ... An inference of nonobviousness is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.” Id. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” Id., quoting Ricoh Co., Ltd. v. Quanta Computer Inc., 550 F.3d 1325, 1332 (Fed. Cir. 2008) (quoting In re Kahn, 441 F.3d 977, 990 (Fed. Cir. 2006)).

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In the background, Pagliuca describes one, and only one, problem intended to be addressed - prior art endoscopic based surgical systems were suitable for small surgical sites but, before Pagliuca’s method, according to Pagliuca, such endoscopic systems had not been developed for fixing vertebra. *See* Pagliuca, paras. [0003]-[0006]. Throughout its lengthy description, Pagliuca describes the importance of creating a significantly larger working space,

compared with conventional endoscopic based surgical systems, for the surgeon within the body, the larger working space being provided by the access devices disclosed in Pagliuca. *See* Pagliuca, para. [0122], [0123], [207], [235], [0246]. One advantage of such a larger working space, according to Pagliuca, is the creation of an “endoscopic operating field at the surgical site” that allows the surgeon to directly visualize the entire working space. *See* Pagliuca, para. [0123]. Pagliuca further describes an extensive support system 120 for supporting an endoscope and describes the presence and use of an endoscope to provide direct visualization of the larger working space provided by the access devices. *See, e.g.,* Pagliuca, para. [0124]-[0126]. In procedures for fixing vertebrae, all of the implants are positioned relative to the vertebrae through the access device in the large, expanded working space provided by the access device and under direct visualization of an endoscope. In one embodiment of Pagliuca, for example, three fasteners 4600 are attached to the vertebra V through the expandable conduit 1020 and a fixation element 4650 is delivered through the expandable conduit 1020 and connected to the housing portions 4604 of the three fasteners 4600. The placement of the fasteners 4600 and the fixation element 4650 is done under direct visualization through endoscope 1502. *See* Pagliuca, para [0273], [0274] and FIGURE 90. One of ordinary skill in the art when reading Pagliuca could only conclude that a larger working space that permits direct visualization of the surgical site with an endoscope was a critical component of the teachings of Pagliuca and that such teachings were Pagliuca’s contributions over prior art endoscopic based surgical systems.

In contrast, Chin describes percutaneous minimally invasive surgical procedures that includes inserting anchors, pedicle screws 140, through separate percutaneous incisions 92a-92f and advancing a connecting device 170, such as a cylindrical rod, subcutaneously to each of the separately positioned pedicle screws 140. These procedures provide “the ability to sequentially connect a fixation device percutaneously between more than two points simultaneously and only directly visualizing the fixation points and not the entire connecting device. This scalable feature is currently a major limitation of other minimally access devices.” *See* Chin, para. [0015] (emphasis added). The “other minimally invasive devices” described in the background of Chin include the endoscopic minimally invasive spinal systems described in U.S. Patent Nos. 5,792,044 and 5,902,231, which are similar to the endoscopic minimally invasive spinal systems described in Pagliuca. *See* Chin, para. [0006]. According to Chin, “[a]nother advantage of this invention is the ability to perform a direct approach to the fixation of two or more points with the

option to place the connecting device beneath the lumbodorsal fascia or through an incision, created by instruments in the lumbodorsal fascia between each fixation points rather than being confined to go beneath the fascia between the fixation points or through a larger opening in the fascia which requires greater tissue expansion and results in greater postoperative pain.” *See* Chin, para. [0015] (emphasis added). One of ordinary skill in the art when reading Chin would conclude that Chin’s discredits prior art endoscopic systems like the system in Pagliuca, and that Chin’s contributions over such systems resulted in increased scalability, minimized tissue expansion from the creation of a large working space, and the resultant trauma caused by such expansion, and, in doing so, limited the surgeons ability to directly visualize the placement of the fixation device (e.g., the spinal rod) during the procedure.

Pagliuca, thus, on the one hand teaches the critical importance of a creating a large working space within the access device by expanding the access device, thereby, permitting direct visualization of the working space through an endoscope, and placement of all of the bone anchors and the spinal fixation through the access device (in the large working space) under direct visualization. On the other hand, Chin discredits the Pagliuca like endoscopic minimally invasive system (as having “limited scalability” and increased tissue expansion) and describes a minimally invasive system that lacks an expandable access device, and, thus, lacks a large working space, and does not permit direct visualization of the entire procedure. Instead, Chin describes inserting anchors, pedicle screws 140, through separate percutaneous incisions 92a-92f and advancing a connecting device 170, such as a cylindrical rod, subcutaneously, without direct visualization, to each of the separately positioned pedicle screws 140. One of ordinary skill in the art would appreciate these contradictory teachings of Pagliuca and Chin and for this reason would be deterred from combining their teachings in the manner asserted by the Examiner.

At most, one of ordinary skill in the art, after evaluating the contradictory teachings of Pagliuca and Chin, would select one of the systems/techniques as a whole or complete replacement or substitute for the other. For example, if the ordinary skilled artisan considered the systems and methods of Chin to be an improvement over the systems and methods of Pagliuca, as asserted by the Examiner, the ordinary skilled artisan would chose to use the entire system and method of Chin (positioning all of the bone anchors through separate percutaneous incisions and advancing the connecting device subcutaneously) rather than combining aspects of

Pagliuca and Chin as proposed by the Examiner. Only with the benefit of the Appellant's disclosure would the ordinary skilled artisan know to combine the teachings of Pagliuca and Chin in the manner proposed by the Examiner.

For this reason, independent claim 47 distinguishes over Pagliuca and Chin and Shulzas, and represents allowable subject matters. Appellant respectfully requests withdrawal of the rejection.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

Dated: October 23, 2009

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APPENDIX A: CLAIMS ON APPEAL

37. (Previously presented) A minimally invasive surgical method comprising:
- making a first incision in a patient;
 - inserting a retractor having a plurality of expandable retractor blades into the first incision;
 - expanding the retractor by separating the retractor blades;
 - advancing a first anchor through the expanded retractor to a first anchor site on a first vertebra;
 - advancing a second anchor through the expanded retractor to a second anchor site on a second vertebra adjacent the first vertebra;
 - making a percutaneous incision in the patient;
 - advancing a third anchor through the percutaneous incision to a third anchor site on a third vertebra adjacent one of the first and second vertebra;
 - positioning a first end of a spinal rod in the expanded retractor;
 - advancing the first end of the spinal rod subcutaneously to the third anchor; and
 - coupling the spinal rod to the first anchor, the second anchor, and the third anchor.
38. (Previously presented) The method of claim 37, wherein the retractor includes a retractor blade having an opening formed therein that is configured to allow the first end of the fixation element to pass therethrough.
39. (Previously presented) The method of claim 37, further comprising creating a second pathway from the percutaneous incision to the third vertebra and advancing the third anchor through the second pathway to the third anchor site.
40. (Previously presented) The method of claim 39, wherein creating a second pathway comprises dilating the percutaneous incision to the third vertebra and inserting a cannula into the dilated percutaneous incision, the cannula defining the second pathway from the percutaneous incision to the third vertebra.

41. (Previously presented) The method of claim 39, wherein the third anchor has a percutaneous access device attached thereto, the percutaneous access device being sized to span from at least the percutaneous incision to the third vertebra, the percutaneous access device having a lumen that defines a second pathway from a proximal end of the percutaneous access device to the third bone anchor.

42. (Previously Presented) The method of claim 41, wherein the percutaneous access device has an opening formed therein to facilitate coupling of the fixation element to the third bone anchor.

43. (Previously Presented) The method of claim 37, wherein the first end of the fixation element is advanced subfascially to the third anchor.

44. (Previously presented) The method of claim 37, further comprising removing disk material from the disk space between the first and second vertebrae through the first pathway.

45. (Previously presented) The method of claim 44, further comprising inserting bone graft into the disk space.

46. (Previously presented) The method of claim 44, further comprising inserting an interbody fusion device into the disk space.

47. (Previously presented) A minimally invasive surgical method comprising:

implanting a first anchor and second anchor in a first vertebra and a second vertebra, respectively, through an expanded surgical retractor positioned in a first incision;

percutaneously positioning a third anchor in a third vertebra adjacent one of the first vertebra and the second vertebra through a percutaneous incision distinct from the first incision;

advancing the first end of a spinal rod subcutaneously from the first incision to the third anchor; and

coupling the spinal rod to the first anchor, the second anchor, and the third anchor.

APPENDIX B: EVIDENCE

No attached evidence.

APPENDIX C: RELATED PROCEEDINGS

No related proceedings.